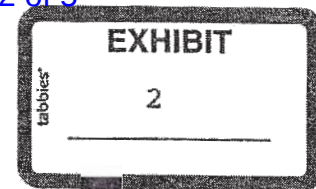# EXHIBIT 8

Written Report

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Background

Over the past 30 years, the use of alarm-enabled medical devices in the clinical environment has become more prevalent with the average number of medical device alarms going from 6 in 1983 to more than 40 in 2011.[1,2] The increase in number of clinical alarms has improved the detection of critical situations, but an unintended consequence is an excessive quantity of alarms, most of which are false or non-actionable, which overwhelm staff and compromise patient safety when staff silence, disable or ignore these warnings.

According to The Joint Commission (TJC), each day, hundreds of auditory alarm signals sound for every patient; thousands of alarm signals ring in every unit; and hundreds of thousands of alarms sound throughout the hospital each day.[3] Research indicates that 85 – 99% of clinical alarms signals do not require intervention.[4-6] The excessive quantity of alarms results in caregiver sensory overload and desensitization. TJC reported 98 alarm-related events between Jan 2009 and June 2012. Of these reported events, 80 resulted in death, 13 in permanent loss of function and 5 in unexpected additional care.[7] The FDA reported 566 alarm-related deaths from 2005 – 2008.[8] It is for this reason that *Alarm Hazards* has been listed as the number one device technology hazard for the past four years and has been in the top three of the medical device hazards list since its inception in 2007 [9](Verbal conversation with Jim Keller, VP ECRI Institute). Alarm hazards is a multifaceted problem and related to

- Too many alarming devices
- Poor device alarm specificity resulting in frequent false alarms so as to not miss a true event
- Staff desensitization to frequent alarm signals
- Unclear alarm accountability by staff
- Large units with inability of staff to hear alarm signals with room doors closed
- Lack of alarm notification systems as an adjunct to medical device alarms
- Competing staff priorities
- Alarms not set to actionable limits

JHH Alarm Management Strategies

Since 2006, Johns Hopkins Hospital (JHH) has spent much time analyzing and implementing alarm management strategies. Alarm assessments performed throughout the hospital demonstrated that monitored units had as many as 700 monitor alarms/bed/day. The majority of these alarms are low priority alarms, many of which are self-correcting, but serve to distract caregivers and disrupt their workflow. A typical monitored unit had an average of 350 alarms/bed/day prior to alarm interventions.

12 Day Sample of Alarm Data	Quantity
High Priority	1587
Medium Priority	6673
Low Priority	48277
Technical Alarms	2227
Grand Total of Alarms	58764
Ave Pt Census	14
Average Alarms/Bed/Day	350

Figure 1: Sample 12 day Monitor Alarm Data

In 2008, Hopkins began a quality improvement project on the Medical Progressive Care Unit aimed at improving staff response to alarms and decreasing the number of non-actionable alarms (Graham and Cvach, 2010). The lessons learned from this unit were expanded to other units throughout JHH. Many more QI projects started and valuable lessons were learned. There was little research evidence on how to reduce alarms and improve alarm response. Hopkins led the work in alarm management and has published numerous articles on alarm reduction strategies including:

- Standardizing alarm settings based on population
- Minimizing duplicate alarm signals
- Setting alarm default thresholds to actionable limits/levels
- Customizing alarms for patients, as needed
- Changing electrodes regularly
- Improving alarm notification through the use of middleware technology, alarm escalation algorithms and use of pagers/phones
- Daily assessment of the need for monitoring

Halsted 8 Alarm Management Barriers

Halsted 8 was an 18 bed medical telemetry unit capable of monitoring up to 12 patients. The unit was located in the historic part of the Hospital which was slated to permanently close in 2014. The plan was to relocate this unit to a newly renovated building in October 2014. Nurses on this unit managed four patients on the day shift and up to five patients on evening and night shift. In 2012, this unit was not equipped with alarm notification equipment such as pagers or phones. There were no monitors at the patient's bedside. Patients wore a telemetry pack and audible monitor alarm signals were only audible at the Halsted 8 nursing station. The unit did not have a dedicated monitor watcher whose job it was to watch and report ECG abnormalities to the nurse. Nurses were responsible for managing their patients' monitors and relied on hearing audible signals from the monitor in determining the level of response required.

Cardiac monitor alarms are hierarchal. The alarm sound is what helps to determine the level of urgency and response required. It was essential that the nurse be able to hear and distinguish a crisis level alarm and respond without delay. The same was true for a Code Blue or Staff Emergency alarms. Nurses did not have pagers or phones as an adjunct for messaging critical information. Because of the frequency of monitor alarms on the unit, many of which occurred simultaneously, it was necessary to hear and view an alarm quickly in order to determine if a response was required.

Halsted 8 had a legacy model nurse call system which relied on overhead paging to notify nurses of patient needs. Since the unit was being closed, there was no plan to renovate Halsted 8 to support wireless alarm notification systems such as pagers and phones. Nurses had to rely on hearing bed/chair alarm signals at the nursing station or while walking through the hallway. Nurses also relied on hearing IV pumps, feeding pumps, respiratory equipment, and other alarm-enabled device sounds emanating from patient rooms. The unit clerk communicated patient call bell needs through overhead paging. A delay in responding to one of these alarms, such as a bed alarm, could result in patient harms.

Cardiac monitor alarm data was not available from Halsted 8 in 2012. There was no mechanism available to capture the data at that time. However alarm data obtained in August 2013 demonstrated that the unit experienced about 400 monitor alarms/bed/day. (See chart below)
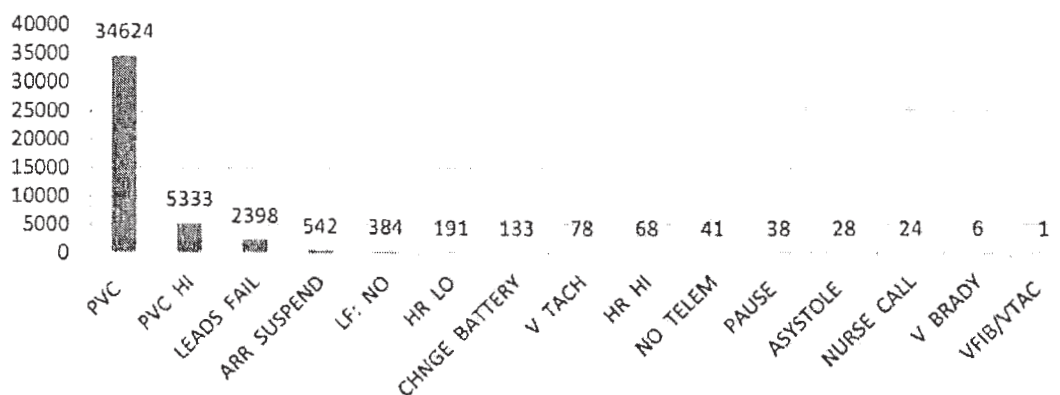

Figure 1: August 2013 Halsted 8 Monitor Alarm Report

Each Halsted 8 nurse managed up to 5 patients. A nurse could potentially experience a significant alarm burden when caring for patients based on the alarms/bed/day.

After getting alarm data from Halsted 8 in August 2013, the Alarm Committee recommended significant changes in their alarm default parameters to reduce alarm burden so that nurses would not be distracted by non-actionable alarm signals. By December, 2013, significant changes were made to the units monitor alarm defaults, which brought the unit down to about 40 monitor alarms/bed/day which was a significant reduction.
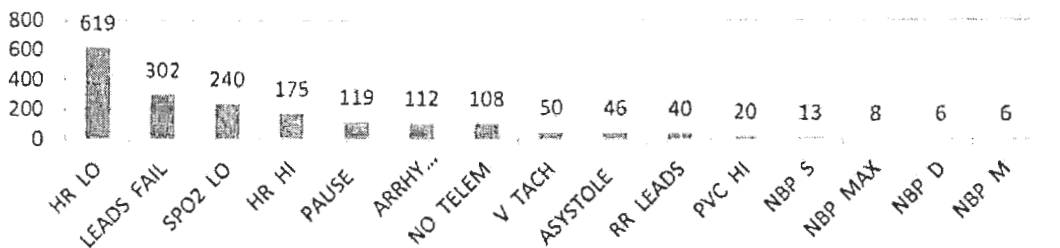

Figure 3: December 2013 Halsted 8 Monitor Alarm Report

Summary

Alarm management is a national patient safety goal and a hospital priority. Sentinel events reported by the Joint Commission indicate that patients have died as a result of alarms being missed. Halsted 8, was a medical telemetry unit with an old infrastructure and equipment which did not support sending alarms to pagers or phones. In 2012, nurses on this unit had to rely on audible alarm signals to determine the level of alarm response that was required. It was critical that the nurses on Halsted 8 be able to hear alarms at the nursing station or while walking in the hallway to determine the level of urgency required for the situation. A deaf nurse would not be able to respond quickly to these alarms. The time it would take to have someone interpret for the deaf nurse could result in a delayed patient response and potential patient injury. The amount of alarms that were occurring in 2012 were significantly higher than in December 2013, when the unit was able to make changes to their monitor alarm default settings, resulting in a more management amount of alarms. Additionally, a delay in the nurse hearing an overhead page or directions during a code situation could have resulted in a delayed response with a potential for patient harm.

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References

1. Kerr JH, Hayes B. An "alarming" situation in the intensive therapy unit. *Intensive Care Med.* 1983;9(3):103-104.

2. Borwoski M, Seibig S, Wrede C, Imhoff M. Reducing false alarms of intensive care online-monitoring systems: An evaluation of two signal extraction algorithms. *Computational and Mathematical Methods in Medicine.* 2011;2011:1-11.

3. Joint Commission. Medical device alarm safety. http://www.jointcommission.org/assets/1/6/medical_device_alarm_safety_infographic.pdf. Updated 2014. Accessed 1/23, 2015.

4. Lawless ST. Crying wolf: False alarms in a pediatric intensive care unit. *Crit Care Med.* 1994;22(6):981-985.

5. Tsien CL, Fackler JC. Poor prognosis for existing monitors in the intensive care unit. *Crit Care Med.* 1997;25(4):614-619.

6. Chambrin MC. Alarms in the intensive care unit: How can the number of false alarms be reduced? *Crit Care.* 2001;5(4):184-188.

7. Joint Commission. The joint commission announces 2014 national patient safety goals. *Joint Commission Perspectives.* 2013;33(7):1-4.

8. Weil KM. Alarming monitor problems. *Nursing.* 2009; 39(9):58.

9. Kit S. ECRI's top 10 health technology hazards for 2014. . 2014.